UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,282	08/28/2001	Pravin Chaturvedi	VPI/01-119	8388

7590 07/15/2002

Andrew S. Marks, Esq.
VERTEX PHARMACEUTICALS INC.
130 Waverly Street
Cambridge, MA 02139-4242

EXAMINER	
ANDRES, JANET L	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 07/15/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,282	CHATURVEDI ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☒ Claim(s) 8-12 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The use of the trademarks CELLCEPT®, INTRON A®, PEGINTRON®, and PEGASYS® has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

2. Claims 8-12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not refer to another multiple dependent claim. Claim 8 depends from claim 5, which is also multiply dependent. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Glue, Seminars in Liver Disease, 1999, vol. 19, suppl. 1, pp. 17-24.

Glue teaches coadministration of interferon alpha and ribavirin to treat hepatitis C. A level of 600 mg twice daily is taught on p. 19. This level is one determined by Applicant's method to be appropriate (p. 14, line 33, and Table 2, p. 16) and thus anticipates claims drawn to

compositions and methods using levels determined by Applicant's method. That Applicant has described a new way of determining a dose already known in the art does not render the dose itself novel.

5. Claims 1, 2, 5-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al., Hepatology, 1999, Vol. 30, No. 4 pt. 2, p. 408A.

Wright et al. teaches the use of VX-497 to treat hepatitis C at the dose determined by Applicant on p. 17 to be optimal and teaches its coadministration with interferon alpha. As stated above, a new means of determining a dose already known does not render the dose itself novel.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 5-9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunet et al., Transplantation Int., 2000, vol. 13, suppl. 1, pp. S301-S305, in view of Markland et al., Antimicrobial Agents and Chemotherapy, 2000, vol. 44, pp. 859-866.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Markland et al. teaches that mycophenolic acid is an IMPDH inhibitor and teaches that such inhibitors are useful in combination with interferon alpha to treat hepatitis C (p. 859). Brunet et al. teaches that 0.5-1.0 g twice a day of mycophenolic acid, which is the range arrived at by Applicant on p. 20, is a useful dose (p. S301). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Markland et al. with those of Brunet et al. to administer 0.5-1.0 g of mycophenolic acid twice a day in combination with interferon alpha to treat hepatitis C. One of ordinary skill would have been motivated to do so because Markland et al. teaches that the combination is useful and Brunet et al. teaches that 0.5-1.0 g/day is an effective dose. One of ordinary skill would thus have expected coadministration of interferon alpha and mycophenolic acid at the stated dose to be a successful treatment for hepatitis C.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3 and 4, and claims 5-12 as they depend from claims 3 and 4, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working

examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

These claims are drawn to methods for optimizing the dosage of IMPDH inhibitors. Applicant has devised an algorithm for this purpose. However, the results set forth in tables 1, 2, and 3 do not appear to provide results for the lower doses predicted by this algorithm to be useful. What is provided are results for higher doses already known to be effective. Thus, there are no working examples presented and no other guidance provided that would allow one of skill to predict that these lower levels would be useful. The prior art does not provide compensatory teachings; only the higher ranges encompassed by Applicant's invention are taught in the art. Thus, one of skill in the art would not be able to predict that the lower doses suggested by Applicant's algorithm would in fact be useful. Without further guidance predictive of a successful outcome, it would require undue experimentation for one of skill in the art to use Applicant's invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 depends from claims 1-7. Thus, it includes the limitations of claim 5, which depends from claims 1-4. It and dependent claims 9-12 thus depend both from claims 1-4 and

from a claim which further limits claims 1-4, and one of skill in the art would not be able to determine the limitations Applicant intended claims 8-12 to encompass.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
July 2, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600